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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/623,464	07/18/2003	Deh-Ming Chang	411-000100US	2980

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EXAMINER	
KIM, VICKIE Y	

ART UNIT	PAPER NUMBER
1618	

DATE MAILED: 08/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/623,464	CHANG, DEH-MING	
	Examiner	Art Unit	
	Vickie Kim	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/05 &4/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. The claims 1-30 are pending and presented for the examination.

Information Disclosure Statement(IDS)

The information disclosure statement (IDS) is submitted on 4/2004 and 2/2005. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner. Please refer to applicants' copy of the 1449 submitted herewith.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-16, 19-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Arghi-Niknam et al(1997, Modulation of immune...) or Yu et al(1999. Attenuation of house dust mite...)

The claims are drawn to a method of modulating a level of IL-10 in a subject, comprising an effective amount of DHEA.

Arghi-Niknam et al teach a DHEA treatment on retrovirus infected mice, where DHEA supplement effectively reduces excessive IL-10 and normalize excessively produced IL-10 level, see abstract and page 346-347, and thus the claims 1, 4, 6-8, 15-20 are met. Arghi-Niknam et al's teaching is directed to a method of retarding the development of murine AIDs or ageing by DEA treatment via normalization of immune response, see page 348, last paragraph.

Secondly, Yu et al also teach a DHEA supplement significant decreases and normalized the numbers of IL-10 where airway inflammation is accompanied by abnormal increased production of IL-10, see abstract and 418 last paragraph.

The claims 2-3, 29-30 are met by Arghi-Niknam et al's or Yu et al's teaching because increased IL-10 level in infected or inflamed subject is measured before DHEA supplement shown in both Yu and Arghi-Niknam et al's teaching, and DHEA supplement normalzied by decreasing IL-10 level, see . As mentioned in Yu et al(see page 415, second paraphr)

Claims 9-11 are also met by the teaching of cited reference because Arghi-Niknam et al or Yu et al utilizes biological sample from mice(serum and fluid) to test its activity in-vivo.

All the critical elements required by the claims are well taught and thus, the claims are anticipated by the cited reference.

3. Claims 1-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Daynes et al(US5518725).

Claims are drawn to a method of modulating a level of IL-10 in a subject, the method comprising selecting a subject in need of a modulated IL-10 and administering an amount of DHEA to the subject wherein the amount is effective to modulate the level of IL-10 in the subject.

Daynes et al(US'725, hereinafter) teaches a vaccine comprising a combination drug of DHEA and vitamin D3 derivatives which provides synergistic enhancement of serum and mucosal antibody response via modifying IL-10 level in serum, see abstract and example 15 at col. 25. Furthermore, US'725 teaches an administration of DHEA(about 10-100mg/day, orally) or DHEA-s or vitamin D3 derivative(e.g. 1,25(OH)2D3 topically or as a component of vaccine enhanced Antibody production, see example 8, col. 19 and col. 14, lines 61-62. Furthermore, US'725 teaches an administration of a DHEA derivative or a vitamin D3 derivative(e.g. 1,25(OH)2D3) as components of vaccine which effectively inhibit antigen to prevent or retard the gropression of infection, see example 8, col. 19 and col. 14, lines 61-62. US'725 further teaches about 10-100mg/day as an effective amount for the activity and various routes of administration including transdermal(=epicutaneous), oral and systemic such as injection, see col 14, lines 50-65.

All the critical elements required by the instant claims are well taught in the cited reference and thus, the claimed subject matter is anticipated by the prior art of the record.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 9-11, 17-18, 21-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Arghi-Niknam et al (1997) in view of Daynes et al(US5518725).

Arghi-Niknam et al's teaching is mentioned in 102 rejection except the claim's limitations which are not explicitly taught by the primary reference(Arghi-Niknam et al). The claims 14, 21-26 are requiring human subject; transdermal administration including topical cream or ointmentwith specific dosage regimen of 25-30 mg/day.

However, it would have been obvious to one of ordinary skill in the art to substitute and modify Arghi-Niknam et al to include these said limitations when Arghi-Niknam et al 's teaching is taken I view of Daynes et al's teaching (US'725, hereinafter) because Daynes et al remedy all the deficiencies found in Arghi-Niknam et al.

US'725 teaches a vaccine which comprises a combination drug treatment of vitamin D3 derivatives and 3 which provides synergistic enhancement of serum and mucosal antibody response via modifying cytokine level in serum, see abstract and example 15 at col. 25. Furthermore, US'725 teaches an administration of DHEA(about 10-100mg/day, orally) or DHEA-s or vitamin D3 derivative(e.g. 1,25(OH)2D3 topically or

as a component of vaccine enhanced Antibody production, see example 8, col. 19 and col. 14, lines 61-62. US'725 further teaches transdermal(=epicutaneous) administrationl

As mentioned in 102 rejection, throughout the disclosure, US725 remedy all the deficiencies found in Arghi-Niknam's teaching, when these references are taken together one would have been apparent to make claimed invention with reasonable expectation of success. One would have been motivated to modify Arghi-Niknam's teaching so that industrial applicability is improved and patient could maximize their benefit.

Conclusion

1. No claim is allowed.

2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is 571-272-0579. The examiner can normally be reached on Tuesday-Friday.
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

VICKIE KIM
PRIMARY EXAMINER

Vickie Kim
August 7, 2006
Art unit 1618